



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

August 31, 2004

**FILE COPY**

Donald O. Beers  
Arnold & Porter LLP  
555 Twelfth Street, N.W.  
Washington, DC 20004-1206

Dear Mr. Beers:

Your petition requesting the Food and Drug Administration to reject NDA 21-695 unless and until the sponsor, Reliant Pharmaceuticals LLC, fulfills its statutory obligations by certifying to all patients properly listed for NDAs 21-203 and 19-304, was received by this office on 08/31/2004. It was assigned docket number 2004P-0386/CP1 and it was filed on 08/31/2004. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe  
Division of Dockets Management  
Office of Management Programs  
Office of Management

2004P-0386

ACK 1